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UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

MEHVA ROFFMAN and LISA CHONG, as individuals, on behalf of themselves, the general public, and those similarly situated,

Plaintiffs,

v.

PERFECT BAR, LLC,

Defendant.

CASE NO. 3:22-cv-02479-JSC

**PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS**

Hon. Jacqueline Scott Corley

Hearing Date: July 28, 2022
Hearing Time: 9:00 a.m.
Courtroom: Remote (Zoom)

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## I. INTRODUCTION

Defendant Perfect Bar, LLC ("Perfect Bar") makes protein a cornerstone of its business. For example, Perfect Bar prominently advertises "7 G PROTEIN" on the front of the Dark Chocolate Perfect Peanut Butter Cups. These front label protein claims, however, are unlawful. FDA regulations *prohibit* manufacturers from making *any* front label protein claims *unless* the manufacturer has: (1) calculated the "corrected amount of protein per serving" based on the quality of the product's protein using the Protein Digestibility Corrected Amino Acid Score ("PDCAAS"); and (2) provided a statement of that corrected amount of protein expressed as percent daily value ("%DV") in the nutrition facts panel ("NFP"). 21 C.F.R. § 101.9(c)(7)(i) & (iii); *see also* 21 C.F.R. §§ 101.13(n) & (b) (conditioning a manufacturer's ability to make front label nutrient content claims upon providing all required information for that nutrient in the NFP). Perfect Bar failed to comply with these FDA requirements for many of its Products, including its Perfect Peanut Butter Cups, Perfect Bites, and Perfect Kids Bars. Perfect Bar does not dispute this. Thus, its front label protein claims (as well as its NFPs) on these products violate parallel federal and state laws and are actionable under the unlawful prong of the UCL.

Perfect Bar misleadingly argues that "[n]o court has endorsed Plaintiffs' assertion that the omission of an FDA-mandated disclosure in the Nutrition Facts panel categorically prohibits it from making front-label statements." ECF 18 at 2. To the contrary, Judge Orrick stated that this claim "appears plausible" in *Brown v. Van's Int'l Foods, Inc*., No. 22-cv-00001-WHO, 2022 U.S. Dist. LEXIS 84477, at *22 (N.D. Cal. May 10, 2022). It is true that he ultimately did not rule on the claim because the plaintiff did not advance that theory of unlawfulness until oral argument, but he nevertheless invited the plaintiff to "include allegations relating to this theory in her amended complaint" implying the amendment would not be futile. *Id*. Accordingly, Perfect Bar's insinuation that courts have ruled against this claim is flat wrong. It is a new claim that no court has yet had the opportunity to review. Here, however, the claim is ripe for review because Plaintiffs' complaint repeatedly alleges that the front label claim is unlawful due to non-compliance with § 101.9(c)(7), and they have raised the argument in their briefing.

Moreover, the FDA's prohibition on front label protein claims in the absence of complete

disclosures in the NFP makes perfect sense. FDA has long emphasized the importance of the NFP and expressed skepticism toward isolated nutrient content claims. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015) ("Under the FDA regulations, the general rule is that 'nutrient content claims' are not permitted on food labels."). The FDA originally created the nutrition facts panel because it determined that stand-alone nutrient content claims could be "misleading for lack of completeness, and could deceive consumers about the nutritional value of the food, its overall contribution to the daily diet, and its nutritional weaknesses." 38 Fed. Reg. 2125.

This is especially true in the protein context where quantity does not present the entire nutritional picture. The FDA imposes tight restrictions on protein labeling because it recognizes that not all proteins provide the same nutritional value. Low quality proteins, such as those Perfect Bar uses, are not fully digestible and are deficient in certain amino acids essential to human protein synthesis. When the human body uses up the least prevalent essential amino acid in a protein source, protein synthesis stops, and the remainder of that protein degrades into waste. The PDCAAS score expresses this as a discount factor that represents the actual amount of protein the product will provide nutritionally. For example, Perfect Bar's products consist of low quality proteins that have a PDCAAS between 0.4 and 0.5, which means they will deliver *less than half* the amount of useable protein they prominently claim on the front label, i.e., only 7 grams of protein (the "corrected amount of protein per serving") instead of the advertised 15. This is why the FDA has explicitly stated that, "protein quantity alone *can be misleading* on foods that are of *low protein quality*." 58 Fed. Reg. 2079 at 2101–2 (emphasis added). As a result, it is not surprising that the FDA *requires* manufacturers to disclose the "corrected amount of protein" in the NFP, as adjusted for protein quality, and otherwise *prohibits* manufacturers from making protein claims if they refuse to do so.

Perfect Bar's only defense to the unlawfulness claims is to argue that they are "impliedly preempted" as seeking to "enforce the FDCA." ECF 18 at 15–17. That is wrong. Plaintiffs are not suing to enforce the FDCA, but California's Sherman Law, which has adopted identical requirements. The overwhelming majority of courts in this district have recognized that the FDCA expressly permits states to adopt identical regulations and provide citizens a private right of action

to enforce those parallel state requirements—meaning the claim cannot be preempted. *See Van's International Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477, at *18 (collecting cases).

The remainder of Perfect Bar's brief largely focuses on Plaintiffs' deception claims. The unlawful and deception claims are distinct and the Court should not conflate them just because Perfect Bar has done so. Plaintiffs' deception claims come in two varieties. The first is that Perfect Bar's protein claims are misleading for the Products identified above due to the omission from the NFP of the statement of the corrected amount of protein. Both Judge Orrick and Judge Gilliam have held that this claim is legally plausible and not preempted, though they have dismissed the claim with leave to amend to add facts that the Plaintiffs relied upon the NFP. *See Van's International Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477, at *17–18, 27; *Brown v. Natures Path Foods, Inc.*, No. 21-cv-05132-HSG, 2022 U.S. Dist. LEXIS 42760, at *11 (N.D. Cal. Mar. 10, 2022). The same result should obtain here.

Plaintiffs' second deception claim is that Perfect Bar's use of the nitrogen method *alone* on the front of the package of all of its Products is misleading due to Perfect Bar's use of low quality proteins, regardless of the NFP. For example, Perfect Bar prominently advertises "15G PROTEIN" on the front of its Dark Chocolate Chip Peanut Butter-flavored Perfect Bar. Although Perfect Bar discloses the %DV on the NFP, the "15G PROTEIN" is misleading because the consumer can only digest 7 grams. Perfect Bar is correct that courts in *this* district have held that this claim is expressly preempted based on FDA regulations that authorize use of the nitrogen method for stating protein quantity *in the NFP*. Plaintiffs believe those cases were wrongly decided. Several courts outside of this district have ruled in Plaintiffs' favor on this issue. *See, e.g., Porter v. NBTY, Inc.* (*Porter I*), No. 15 CV 11459, 2016 U.S. Dist. LEXIS 163352, at *17–18 (N.D. Ill. Nov. 28, 2016); *Ulrich v. Probalance, Inc.*, No. 16 C 10488, 2017 U.S. Dist. LEXIS 132202, at *11–12 (N.D. Ill. Aug. 18, 2017); *Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2016 U.S. Dist. LEXIS 32759, at *40 (N.D. Ill. Mar. 15, 2016). Plaintiffs ask that this Court follow those cases. Regardless, it has no impact on the analysis of Plaintiffs' unlawfulness claims as to the front label or the NFP, or Plaintiffs' misleading by omission claim, all of which directly track the regulations and cannot be preempted.

## II. BACKGROUND

### A. Protein Quality Generally.

Consumers' desire for high protein products, and, correspondingly, the number of products making protein claims, has exploded recently. ECF 1, ¶ 2, 20. But proteins are not a monolithic substance. They are chains of amino acids that come in many different varieties, some of which humans can use more fully and readily than others. *Id.* ¶ 24; *see also* 21 C.F.R. § 101.9(c)(7)(i)–(ii). Of the 20 total amino acids, humans cannot produce nine of them on their own; those amino acids, known as essential amino acids, must be obtained through the diet. *Id*. at ¶ 25. "[P]rotein quality is a measure of the content, proportion, and availability of essential amino acids in food protein." 56 Fed. Reg. 60366, § B.

A protein's quality is critical from a nutritional perspective because the human body requires nine essential amino acids to synthesize the human proteins necessary for life. ECF 1 at ¶ 26. Lacking even one essential amino acid will prevent protein synthesis from occurring, and the remainder of the amino acids from that protein source simply degrade into waste. *Id.* Accordingly, once the body uses up the limiting essential amino acid from a protein source, the remainder of that protein becomes useless to human protein synthesis and of little nutritional value in general. *Id.* A protein source's quality, and its usefulness in human nutrition, also depends upon how digestible it is. *Id.* at ¶ 27. Whatever portion of a protein is non-digestible will simply pass through the body without being absorbed or used at all. *Id*.

As the FDA recognizes, "[a]ccurate methods for determining protein quality are necessary because different food protein sources are not equivalent in their ability to support growth and body protein maintenance." 56 Fed. Reg. 60366, § B. PDCAAS is the FDA mandated measure of protein quality and it accounts for both the proportion of essential amino acids in the protein source and its digestibility. PDCAAS combines these two facets into a discount factor (e.g., 0.5) that, when multiplied by protein quantity in grams, shows how much protein a product actually provides for human nutritional purposes, also in grams. *Id*. at ¶ 29. FDA regulations refer to this as the "corrected amount of protein per serving." *See* 21 C.F.R. § 101.9(c)(7)(i)–(ii).

**B. The Regulatory Framework.**

FDA regulates what manufacturers may say about protein. In so doing, the regulations recognize the critical distinction between protein quality and quantity. They also contain specific requirements for protein-related statements that account for both quality and quantity in a product's NFP.

All NFPs must state the quantity of grams of protein per serving. 21 C.F.R. § 101.9(c)(7). Manufacturers "may" use nitrogen testing or other methods to calculate that quantity. 21 C.F.R. § 101.9(c)(7). The nitrogen method estimates protein quantity by multiplying the nitrogen content of a food by a standardized conversion factor; the NFP protein-quantity statement does not account in any way for the quality of a protein source.

Statements about protein outside of the NFP (e.g., on the front of a package) are purely voluntary, but subject to a higher bar than NFP statements due to the impact of voluntary label claims on purchasing decisions. *See* 21 C.F.R. § 101.9(c)(7)(i)–(ii). Most importantly, the FDA permits voluntary protein claims outside of the nutritional fact panel *only if* the manufacturer satisfies certain requirements. Section 101.9(c)(7)(i) provides that if a product makes a "protein claim" the manufacturer "*shall*" (1) calculate the "corrected amount of protein per serving" using the PDCAAS method, and (2) provide a "statement of the corrected amount of protein" inside the NFP immediately adjacent to the protein quantity figure "expressed as" a %DV. The purpose of this is to inform consumers about the amount of protein in the product the human body can actually use. ECF 1 at ¶¶ 4–5, 37. As the FDA explained in published guidance, it implemented this requirement because when a manufacturer voluntarily touts protein to increase its sales, the FDA wanted to ensure consumers could "readily identify foods with particularly low quality protein to *prevent them from being misled by information on only the amount of protein present*." 58 Fed. Reg. 2079, 2102 (emphasis added).

If there were any doubt, the FDA regulations that govern front label claims (i.e., nutrient content claims) also provide that Perfect Bar's failure to comply with section 101.9(c)(7)(i) barred it from making front label protein claims. Section 101.13(n) states that "[n]utrition labeling in accordance with § 101.9, § 101.10, or § 101.36, as applicable, shall be provided for any food for

which a nutrient content claim is made." Section 101.13(b) in turn provides that "a nutrient content claim[] may not be made on the label or in labeling of foods unless the claim is made in accordance" with all of § 101.13, which includes § 101.13(n), and, thus, by extension, § 101.9(c)(7)(i). In other words, these regulations make the ability to put a nutrient content claim on the front label *contingent* upon compliance with § 101.9 and confirm that Perfect Bar could not make front label protein claims for Products such the Perfect Peanut Butter Cups, Perfect Bites, and Perfect Kids Bars (see ECF 1 at ¶¶ 6 & 19) because it did not state the "corrected amount of protein" in the NFP in compliance with § 101.9(c)(7)(i). Indeed, the FDA has explicitly stated that section 101.13(n) means a manufacturer can only make "a nutrient content claim . . . on the label or in labeling of a food, *provided* that the food bears nutrition labeling that complies with the requirements in proposed § 101.9." 58 Fed. Reg. 2302, 2310 (emphasis added).

The FDA also subjects front label claims to heightened scrutiny through § 101.13(i)(3), which prohibits claims about the "amount or percentage of a nutrient" like protein on the front label if it is "false or misleading in any respect." This applies even if the claim is "permitted or required" inside the NFP. In particular, Section 101.13(c) provides that statements made inside the NFP are not nutrient content claims *but* "[i]f such information is declared *elsewhere* on the label or in labeling, it is a nutrient content claim and *is subject to the requirements for nutrient content claims*." So, a claim like "15g Protein" when made inside the NFP is not a nutrient content claim, but § 101.13(c) transforms it into a nutrient content claim and subjects it to all the rules associated with nutrient content claims when it is made outside the NFP. Through § 101.13(c), FDA envisions that some claims that are permissible inside the NFP may be misleading when made outside the context of the NFP, and particularly without all of the required information that is supposed to be disclosed inside the NFP.

**C. Perfect Bar's Labels.**

Perfect Bar is aware of consumers' increased desire for protein products and therefore touts protein content on the front labels of many of its products. ECF 1 at ¶ 2; Ex. B to ECF 1. Perfect Bar's Chocolate Chip Perfect Kids Bar and Dark Chocolate Mint Peanut Butter Cup advertise "7G Protein" on their labels. But nowhere on the packaging—in the NFP or elsewhere—

does Perfect Bar include any information on the product's poor protein quality or low PDCAAS score. ECF 1, ¶¶ 6 & 19. Other Perfect Bar products include the %DV only on the back, but still prominently advertise their protein content on the front label. For example, its Dark Chocolate Chip Peanut Butter Bar,[1] prominently advertises "15G PROTEIN" on its front label, without disclosing anything on the front label to educate consumers regarding how much of this protein is digestible. *Id*. at ¶¶ 2 & 56. But Perfect Bar's products use plant-based protein as protein sources, which typically have PDCAAS scores of between 0.4 and 0.5, which means that the corrected amount of protein per serving is only between 6–7.5 grams for the "15G Protein" Perfect Bar and 2.8–3.5 grams for the Kids Bar and Peanut Butter Cup products. Accordingly, at least ***half*** of the protein Perfect Bar advertises on its products' front labels is useless to humans, which makes its prominent advertisement of "15G PROTEIN" misleading. *Id*. at ¶ 19, 30. Many of Perfect Bar's protein claims are unlawful, and all mislead consumers.

## III. LEGAL STANDARD

To survive a motion to dismiss, a complaint need only contain "enough facts to state a claim [for] relief that is plausible on its face." *Twombly*, 550 U.S. at 570. A claim is plausible when it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In evaluating plausibility, "the court must presume all factual allegations are true and draw all reasonable inferences in favor of Plaintiff." *Theranos, Inc. v. Fuisz Pharma LLC*, 876 F. Supp. 2d 1123, 1136 (N.D. Cal. 2012) (citing *Twombly*, 550 U.S. at 570; *Iqbal*, 556 U.S. at 678).

## IV. ARGUMENT

### A. Plaintiffs' Unlawful Prong Claims Withstand Dismissal.

#### 1. Plaintiffs adequately pleaded their unlawful prong claims.

Section 17200's "unlawful" prong "borrows violations of other laws and makes those unlawful practices actionable under the UCL." *Klein v. Chevron U.S.A., Inc.*, 137 Cal. Rptr. 3d 293, 326–27 (Cal. Ct. App. 2012) (internal quotation marks and ellipsis omitted). "Virtually any law or regulation—federal or state, statutory or common law—can serve as a predicate for a

[1] All the products are sold under the "PERFECT" brand name. *See* Ex. B to ECF 1.

section 17200 'unlawful' violation." *Id.* (internal quotation marks and ellipsis omitted); *see also Friedman v. AARP, Inc.*, 855 F.3d 1047, 1052 (same). This includes, as here, violations of California's Sherman Law. *See Morgan v. Wallaby Yogurt Co.*, No. 13-cv-00296-WHO, 2013 U.S. Dist. LEXIS 144959 *28–30 (N.D. Cal. Oct. 4, 2013) (Orrick, J.) (allowing UCL unlawfulness claims based on predicate violations of the Sherman Law to proceed).

Plaintiffs' UCL unlawful prong claim alleges that Perfect Bar violated the Sherman Law (which adopts the FDA regulations) by making a protein claim on the front label even though it failed to meet the federally (and state) mandated requirements for making that claim. ECF 1 at ¶¶ 5–6, 32–33. Section 101.9(c)(7)(i) is clear: if a product makes a "protein claim" the manufacturer "*shall*" calculate the "corrected amount of protein per serving" using PDCAAS, and provide a statement to consumers of that corrected amount per serving expressed as a %DV in the NFP. The converse is necessarily true—without having calculated the PDCASS and provided a statement of the corrected amount of protein expressed as a %DV, a manufacturer *shall not* make *any* protein claim. There is no way to construe the regulation to permit a front label protein claim in the absence of the necessary information in the NFP. Because Perfect Bar's products failed these requirements, it was not permitted to make any protein claims on the front label, which claims were *always* unlawful per se. This stems not only from § 101.9(c)(7)(i) itself, but also from § 101.13(n), which provides that "[n]utrition labeling in accordance with § 101.9…*shall be provided for any food for which a nutrient content claim is made*," and § 101.13(b), which, in turn, states "a nutrient content claim[] *may not be made on the label…unless the claim is made in accordance with this regulation* [i.e., § 101.13] . . . ." Moreover, the FDA made clear when promulgating § 101.13(n) that it means a manufacturer can only make "a nutrient content claim . . . on the label or in labeling of a food, *provided* that the food bears nutrition *labeling that complies with the requirements in proposed § 101.9*." 58 Fed. Reg. 2302, 2310 (emphasis added).

These regulations reflect the FDA's long-standing emphasis on the importance of the NFP—which provides a more holistic view of the nutritional value of a product—and its general skepticism of isolated nutrient content claims. *See Reid*, 780 F.3d 952 ,at 959 ("Under the FDA regulations, the general rule is that 'nutrient content claims' are not permitted on food labels.").

Indeed, the FDA originally created the nutrition facts panel because it determined that standalone nutrient content claims could be "misleading for lack of completeness, and could deceive consumers about the nutritional value of the food, its overall contribution to the daily diet, and its nutritional weaknesses." 38 Fed. Reg. 2125. This was the primary motivating factor for the FDA in promulgating section 101.13(n). As it explained at the time: "[n]utrition labeling is necessary when a [nutrient content] claim is made to ensure that other important nutritional aspects of the food are presented along with that aspect highlighted by the claim." 58 Fed. Reg. 2302, 2310.

In the protein context, that manifests in the differences between protein quantity and protein quality, which represent different nutritional aspects of the food. The FDA knows that quantity by itself does not present the full nutritional value of the product and that in low quality protein products quantity alone is misleading due to the way proteins are absorbed in the human body. Accordingly, to address the problem, FDA ensures that anyone who highlights protein quantity must also describe the protein's quality to consumers in the NFP by providing a statement of the corrected amount of protein per serving (i.e., quantity adjusted for quality) expressed as a %DV. 21 C.F.R. §§ 101.9(c)(7)(i), 101.13(n) & (b). In so doing, the FDA ensures consumers are presented with the other "important nutritional aspect "of the product's protein—its quality—and it prevents manufacturers from masking the "nutritional weakness" of their food by touting only protein quantity.

The upshot is that the FDA conditions a manufacturer's ability to make a front label nutrient content claim upon compliance with § 101.9's labeling requirements as to that nutrient in the NFP. Because Perfect Bar did not state the "corrected amount of protein" in the nutrition facts panel (NFP) on the *back panel* in compliance with § 101.9(c)(7)(i), its *front label* protein claim was unlawful. Period.

Plaintiffs have also adequately alleged standing to pursue this claim, i.e., reliance and injury. Where a plaintiff pleads reliance on an unlawful labeling statement, and payment of a price premium as a result, they have alleged a cognizable economic injury for purposes of both statutory and Article III standing. *See Swearingen v. Amazon Pres. Partners, Inc.*, No. 13-cv-04402-WHO, 2014 U.S. Dist. LEXIS 36830, at *7 (N.D. Cal. Mar. 18, 2014) (reliance on unlawful label claim

provides statutory standing to pursue unlawful prong UCL claim); *Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 989 (9th Cir. 2015) (paying more for a product is a quintessential economic injury). Perfect Bar does not dispute that Plaintiffs adequately alleged reliance on the front label and payment of a price premium as a result. *See* ECF 1 at ¶¶ 52–55, 75.[2]

Perfect Bar's only reliance argument is that Plaintiffs have not adequately alleged reliance on the NFP. But that is irrelevant to Plaintiffs' front label unlawfulness claim. The law is clear, "plaintiffs are required to plead and prove that they actually relied *on the statement at issue*." *Nacarino v. Chobani, LLC*, No. 20-cv-07437-EMC, 2022 U.S. Dist. LEXIS 20671, at *19 (N.D. Cal. Feb. 4, 2022) (emphasis added). Here, the statement at issue and what Plaintiffs allege to be unlawful and injury-producing under *this claim* is the front label protein claim. While Perfect Bar's failure to comply with § 101.9 and state the "corrected amount of protein" in the NFP is the *reason* the front label protein nutrient content claim is unlawful, *see* 21 C.F.R. §§ 101.13(n) & (b) (prohibiting nutrient content claims absent compliance with § 101.9), and serves as the basis for some of Plaintiffs' other claims, it is not the injury-producing statement at issue for this claim.[3]

**2. Plaintiffs' unlawful prong claims are not expressly preempted.**

The preemption provision of the Food, Drug, and Cosmetic Act ("FDCA") expressly preserves parallel or identical state law claims. *See* 21 U.S.C. § 343-1(a)(5); *see also Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018). Congress limited preemption to only those state laws that "impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA." *Krommenhock v. Post Foods, LLC*, 255 F. Supp. 3d 938, 951 (N.D. Cal. 2017). Here, Plaintiffs' unlawful prong claims allege that Perfect Bar failed to comply with the regulatory prerequisites for making a protein claim by failing to include required information for protein in

[2] Under the unlawful prong, Plaintiffs must allege reliance ***not*** because the claim requires substantive proof of deception—it does not—but because otherwise "purchasers who never 'viewed the defendant's advertising' . . . would have standing to sue [which] is inconsistent with Proposition 64." *Swearingen v. Amazon Pres. Partners, Inc.*, 2014 U.S. Dist. LEXIS 36830, at *7 (N.D. Cal. Mar. 18, 2014) (quoting *Kane v. Chobani, Inc.*, No. 12-CV-02425-LHK, 2013 U.S. Dist LEXIS 134385 *33-34 (N.D. Cal. Sept. 19, 2013)); *see also id.* ("the reasonable consumer test [for deception] does not apply to the plaintiff's claims under the unlawful prong of the UCL predicated on Sherman Law violations.").

[3] Plaintiffs address reliance on the NFP in the section dealing with their deceptive omission claim.

the NFP. The claims directly track the regulations, impose no different or additional requirements, and, therefore, cannot be expressly preempted. *See Van's Int'l Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477, at *18 (holding that the FDCA did not expressly preempt a UCL unlawful prong claim based on use of front label protein claim without a %DV in the NFP).

Perfect Bar begins its motion by arguing that the FDA allows manufacturers to make quantitative protein content claims outside of the NFP based on nitrogen-testing, citing to both 21 C.F.R. § 101.13(i)(3), and § 101.9(c)(7)(i) for support. *See* ECF 18 at 3–4 and 7–9. But that argument misses the point with regards to Plaintiffs' front label unlawfulness claim. That claim does not turn on Perfect Bar's use of the nitrogen method (as opposed to PDCAAS method) to calculate protein content on the front label, or require any digestibility adjustment on the front label. Rather, Plaintiffs allege that *any front-label protein claim is unlawful in the absence of a statement of the corrected amount of protein in the NFP*. In other words, even assuming, *arguendo*, that § 101.13(i)(3) otherwise authorized Perfect Bar to make a nitrogen-based quantity claim on the front, that does not allow the Perfect Bar to bypass the rest of § 101.13, which clearly requires compliance with the NFP regulations prior to making any nutrient claim at all. Indeed, § 101.13(b) is explicit that a manufacturer may not make any nutrient content claim unless it fully complies with *all of the provisions* of § 101.13, which necessarily includes § 101.13(n), and thus, by extension, § 101.9(c)(7)(i). And, although § 101.9(c)(7)(i) does "contemplate the possibility" of front label protein claims (ECF 18 at 7), it very clearly does so *only under the conditions* specified therein, i.e, upon inclusion of the required information on protein quality in the NFP. Perfect Bar does not get to pick and choose which portions of §§ 101.13 or 101.9(c)(7)(i) with which it will comply; it must comply with every provision, or make no protein claims.

Accordingly, Perfect Bar's argument that the FDA allows use of nitrogen-testing to calculate protein content is irrelevant to Plaintiffs' unlawfulness claims. None of the FDA's "guidance" statements that Perfect Bar submitted to support its preemption argument permit *any* front-label protein claims—whether based on nitrogen-testing or PDCAAS—without a %DV in the NFP based on the corrected protein value. Two are silent on the issue. See RJN, Exs. 1 & 3. The third, which Perfect Bar touts extensively, clearly states that any front-label protein content

claim requires the NFP to include the corrected amount of protein per serving, which Perfect Bar omitted. RJN, Ex. 2 at p.2 ("[W]hen a quantitative statement about protein is made outside of the Nutrition Facts label, the percent Daily Value for protein *must be declared within the Nutrition Facts label* and it *must be calculated using the corrected amount of protein per serving* (see 21 CFR 101.9(c)(7)(i)).") (emphasis added). So even the FDA guidance upon which Perfect Bar relies supports the conclusion that Plaintiffs adequately pled a UCL unlawful claim.

Perfect Bar's extensive reliance on *Nacarino v. Kashi Co.*, No. 21-cv-07036-VC, 2022 U.S. Dist. LEXIS 23409, at *8 (N.D. Cal. Feb. 9, 2022), and its progeny on express preemption, is also entirely misplaced as to Plaintiffs' unlawful prong claims. Those cases analyzed express preemption solely in the context of whether state law could require a manufacturer to use PDCAAS to calculate a front label protein claim, as opposed to the nitrogen method, and determined such a claim was expressly preempted. None of them analyzed the unlawfulness claim Plaintiffs assert here.

**3. *Buckman* preemption does not apply.**

Perfect Bar next argues that the unlawfulness claim is impliedly preempted under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)—a theory courts in this district have repeatedly and squarely rejected. *See, e.g.*, *Brown's v. Van's Int'l Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477, at *22–23, quoting *Vassigh v. Bai Brands, LLC*, No. 14-cv-05127-HSG, 2015 U.S. Dist. LEXIS 90675, at *13; *Vassigh*, 2015 U.S. Dist. LEXIS 90675, at *12–13 ("[C]ourts in this District . . . routinely reject the argument that the Court's reasoning in *Buckman* justifies preemption of food labeling claims under the Sherman Law."). In essence, Perfect Bar advocates for the Court to apply a novel interpretation of *Buckman* that incongruously *impliedly* preempts the same claims that the FDCA preemption provision *expressly* allows. "[A] number of courts have rejected this contention," and for good reason. *Morgan v. Wallaby Yogurt Co.*, No. 13-cv-00296-WHO, 2013 U.S. Dist. LEXIS 144959 *19–24 (N.D. Cal. Oct. 4, 2013)**Error! Bookmark not defined.** (collecting cases).

In a recent opinion, Judge Orrick conducted an in-depth analysis of whether *Buckman* impliedly preempts UCL unlawful claims predicated on violations of the Sherman Law (which

adopts the FDA regulations) and concluded it does not. *Van's Int'l Foods*, 2022 U.S. Dist. LEXIS 84477, at *18–23. Ultimately, he sided with the vast majority of courts in this District and declined to apply *Buckman*. He reasoned that, "[s]tates have traditionally possessed the power to protect their citizens from fraud and deception in the sale of food, and therefore there is a strong presumption against federal preemption in the area of marketing food." *Id*. at *19. When Congress enacted the nutrition labelling laws, it "did not attempt to completely preempt state laws regarding the marketing of food products"; rather, it "specifically anticipated states enacting their own identical laws." *Id*. Since Congress expressly left the door open to parallel state laws, "California complied with this requirement in passing the Sherman Law," which incorporates the federal regulations. *Id*. at *19–20 Thus, claims based on the Sherman Law fit through the "narrow gap" that avoids preemption. *Id*. at *21.

For these same reasons, courts in this district "routinely . . . reject the argument that the Supreme Court's reasoning in *Buckman* justifies presumption of food labelling claims under the Sherman Law." *Van's Int'l Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477, at *22–23, quoting *Vassigh*, 2015 U.S. Dist. LEXIS 90675 at *13 (Gilliam, J.).[4]

Perfect Bar rests its implied preemption argument on Judge Seeborg's decision in *Chong v. KIND LLC*, --- F. Supp. 3d ----, No. 21-cv-04528-RS, 2022 WL 464149, at *4 (N.D. Cal. 2022). But *Chong* is the lone outlier from this district's otherwise universal rejection of applying *Buckman* preemption to UCL unlawful prong claims based on the Sherman Law. Further, *Chong*'s holding is based on the erroneous assumption that statutes must predate the FDCA to avoid being impliedly preempted—a proposition Judge Orrick rejected on essentially identical facts. *See Van's Int'l Foods*, 2022 U.S. Dist. LEXIS 42760 at *18-23. As Judge Orrick reasoned,

[4] For additional cases rejecting *Buckman* preemption, *see also De Keczer v. Tetley USA, Inc*., No. 5:12-CV-02409-EJD, 2014 U.S. Dist. LEXIS 121465, at *16–17 (N.D. Cal. Aug. 28, 2014) (Davila, J.); *Hendricks v. StarKist Co*., 30 F. Supp. 3d 917, 926 (N.D. Cal. 2014) (Gonzalez Rogers, J.); *Ross v. Clover Stornetta Farms*, No. C -13-01517 EDL, 2014 U.S. Dist. LEXIS 5408, at *27–28 (N.D. Cal. Jan. 14, 2014) (Laporte, J.); *Gustavson v. Wrigley Sales Co*., 961 F. Supp. 2d 1100, 1117 (N.D. Cal. 2013) (Koh, J.); *Sciortino v. PepsiCo, Inc*., 108 F. Supp. 3d 780, 807–08 (N.D. Cal. 2015) (Chen, J.); *Swearingen v. Santa Cruz Nat., Inc*., No. 13-cv-04291-SI, 2016 U.S. Dist. LEXIS 109432, at *20 (N.D. Cal. Aug. 17, 2016) (Illston, J.); *Clancy v. Bromley Tea Co*., 308 F.R.D. 564, 575 (N.D. Cal. 2013) (Tigar, J.); *Samet v. P&G*, No. 5:12-CV-01891 PSG, 2013 U.S. Dist. LEXIS 86432, at *23–24 (N.D. Cal. June 18, 2013) (Grewal, J.)

"*Chong* cites language from the *Stengel* concurrence" to find that the law must predate the FDCA. *Id.* at 22 (quoting *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1235 (9th Cir. 2013) (Watford, J., concurring). By contrast, the majority in "*Stengel* actually held that the FDCA 'does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the [FDCA].'" *Id.*, (quoting *Stengel*, 704 F.3d at 1228 (en banc)).

*Chong* is also subject to a pending appeal, so it is not settled law. *See Chong, et. al. v. Kind LLC*, No. 22-15368 (9th Cir.). The only other case Perfect Bar cites in support of *Buckman* preemption is *Borchenko v. L'Oreal USA, Inc.*, 389 F. Supp. 3d 769, 772–74 (C.D. Cal. 2019), which is distinguishable because it involved a plaintiff's attempt to enforce the FDA's premarket approval process for a putative "new drug"; unlike *Borchenko*, Plaintiffs here are not trying to do the FDA's job.

### B. Plaintiffs Adequately Pled their CLRA, Fraud, and False Advertising Claims.

Plaintiffs have also adequately alleged deception claims under the UCL's fraud prong, the CLRA, the FAL, and common law fraud. Plaintiffs present two distinct deception/fraud theories. First, the Complaint alleges that Perfect Bar's front label claims, which omit a statement of the corrected amount of protein in the NFP, are deceptive because they lead consumers to believe that all the advertised protein will be bioavailable. Second, the Complaint alleges that Perfect Bar's standalone, nitrogen-based protein quantity claims on the front label are misleading by virtue of the low quality protein in Perfect Bar's products.

Perfect Bar moves to dismiss these claims based on two arguments. First, that the claims are preempted because the FDA has approved the use of front-label protein content claims based on nitrogen-testing. Second, that Plaintiffs have failed to allege reliance on the %DV value. Both arguments fail.

#### 1. Plaintiffs' deceptive omission claims are not expressly preempted.

As noted above, Plaintiffs first theory of deceptive conduct is that Perfect Bar has deceived consumers by using a front-label protein content claim that overstates digestible protein without including a qualifying %DV statement in the NFP. This fraud-by-omission claim is also based on 21 C.F.R. § 101.9(c)(7)(i), and the same preemption analysis discussed above in conjunction with

Plaintiffs' unlawful prong claims applies here. Judge Orrick held that this claim was not preempted. *See Van's*, 2022 U.S. Dist. LEXIS 84477, at *17–18 ("Brown's theory that the front label claim is misleading because of the missing information in the Nutrition Facts panel . . . is not expressly preempted by FDA regulations because it is based on an alleged violation of FDA regulations. See 21 C.F.R. § 101.9(c)(7)(i).").

**2. Plaintiffs can amend to add facts about their reliance on the NFP.**

Plaintiffs acknowledge that the complaint is currently silent about their reliance on the NFP. However, Perfect Bar is wrong to assert that Plaintiffs "cannot plausibly allege that the omission of the 'corrected amount of protein' from the Nutrition Facts panel affected their purchasing decisions" just because they have also alleged "that they purchased Perfect Bar's products 'after reading and relying on the product front labels.'" ECF 18 at 13. Reading and relying on the front does not preclude also reading and relying on the back, and the court cannot draw an inference of non-reliance *against* Plaintiffs at this stage of the case from their current silence. Plaintiffs certainly can allege that they read and relied upon the NFP prior to purchase and that Perfect Bar's disclosure of the corrected amount of protein per serving would have altered their behavior, which is more than sufficient to meet the standard. *See Baranco v. Ford Motor Co.*, 294 F. Supp. 3d 950, 967 (N.D. Cal. 2018) (summarizing California law on reliance for consumer protection claims and stating that a plaintiff establishes reliance on an omission by alleging she likely would have "behaved differently" if the omitted information had been disclosed). Accordingly, the Court should grant Plaintiffs leave to amend to add these facts.

Indeed, despite relying heavily on the *Nature's Path* and *Van's* rulings, Perfect Bar fails to mention that *both* Judge Orrick and Judge Gilliam granted leave to amend on the issue of reliance. In so doing, Judge Orrick explicitly held that "the protein claim on the front label is plausibly misleading *because* Sara Lee failed to include the required protein digestibility-adjusted figure on the Nutrition Facts label." *Van's Int'l Foods, Inc.*, 2022 U.S. Dist. LEXIS 84477 at *27. The only thing missing were "facts that would show that she looked at the Nutrition Facts label during the process of purchasing the Products." *Id.* Accordingly, Judge Orrick dismissed "with leave to amend so that she may allege whether she saw and relied upon the Nutrition Facts labels

for the Products at issue," and he did so despite the fact that the Plaintiffs there alleged that they relied upon the products' front label protein claims prior to purchase. *Id.* at *27, 7.

Similarly, Judge Gilliam stated that, by dismissing this claim, "[t]he Court does not mean to imply that Plaintiffs could not possibly have been deceived by Nature's Path's alleged omission of the percent daily value figures." *See Natures Path Foods, Inc.*, 2022 U.S. Dist. LEXIS 42760, at *11. As the Court noted, the claim "is not so factually implausible that dismissal is necessarily warranted on the pleadings." *Id.* Accordingly, the Court dismissed "but with leave to amend" to add allegations that they relied upon the NFP, and, again, despite allegations that the plaintiffs read and relied on the Products front labels. *Id.*

Finally, Perfect Bar's reliance on *Shaeffer v. Califia Farms, LLC*, 44 Cal. App. 5th 1125 (2020) as "illustrative" misses the mark as well. (ECF 18 at 13.) In *Shaeffer*, the court dismissed a claim that juice was mislabeled due to the defendant's failure to disclose it was not "low calorie" or "calorie reduced." There dismissal was appropriate because the plaintiff's allegations failed to include any allegations that she was purchasing the food based on calorie content. Here, in contrast, Plaintiffs have alleged that their purchasing decisions were based on protein content expressed on the front label, so it is plausible for them to also allege that they relied on protein representation made on the back label, and that their decisions would have changed if the %DV had been disclosed.

**3. Plaintiffs' fraud and deception claims based on Perfect Bar's use of nitrogen-test protein values are not preempted.**

Plaintiffs acknowledge that courts in this district have found in favor of express preemption on the claim that a standalone nitrogen-based protein quantity representation on the front label is independently misleading, regardless of the NFP. However, Plaintiffs respectfully disagree with these decisions and ask the Court to take a different approach. As explained above, the FDCA preemption provision expressly preserves parallel or identical state law claims. *See* 21 U.S.C. § 343-1(a)(5); *see also Hawkins* at 769. Moreover, when assessing preemption, courts must "start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted);

*see also Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products."); see also *Stengel*, 704 F.3d at 1227 (presumption of no preemption can only be overcome by considerable evidence).

Here, state and federal law agree that statements about the "amount or percentage of a nutrient" like protein cannot be "false or misleading in any respect" when made on the front of a package. 21 C.F.R. § 101.13(i)(3). And, when promulgating § 101.9(c)(7)—the same regulation Perfect Bar claims authorizes its front label claims—the FDA stated that "*protein quantity alone can be misleading on foods that are of low protein quality*." 58 Fed. Reg. 2079 at 2101–2 (emphasis added). This is because the FDA knows that "different food protein sources are not equivalent in their ability to support growth and body protein maintenance." 56 Fed. Reg. 60366, § B. The FDA also knows that nitrogen testing values alone can be misleading.

Thus, with respect to Plaintiffs' second fraud theory—that use of nitrogen-test protein values on the front label are misleading—Perfect Bar's express preemption argument fails because Plaintiffs' fraud (UCL, FAL, and common law) and CLRA claims are identical to the requirements of §§ 101.9 and 101.13. *See Lily v. ConAgra Foods, Inc*., 743 F. 3d 662, 663 (9th Cir. 2014) (UCL, CLRA, and FAL claims that front label deceptively misstated salt content were not preempted because they "impose no greater burden than those imposed by federal law"); see also *Pardini v. Unilever United States, Inc.*, No. 13-1675 SC, 2014 U.S. Dist. LEXIS 7900, at *20–21 (N.D. Cal. Jan. 22, 2014) (state law fraud claims based on failure to include qualification of nutrient content claim required by 21 C.F.R. § 101.13 not preempted by FDCA). Indeed, every court to address this question prior to *Nacarino* held that these exact claims were not preempted. *See, e.g., Ulrich*, 2017 U.S. Dist. LEXIS 132202, *11–12; *Porter I*, 2016 U.S. Dist. LEXIS 163352 at *17–18; *Gubala*, 2016 U.S. Dist. LEXIS 32759, *40.

*Porter I* is instructive. There, the front label claim was "60g Premium Protein."[5] *Porter I*, 2016 U.S. Dist. LEXIS 163352 at *4. Although, as here, nitrogen testing supported the front label

[5] Use of the term "premium" in *Porter* makes no difference. The protein claim was misleading because the product did not provide the amount of protein claimed. *Porter I*, 2016 U.S. Dist. LEXIS 163352 at *4. As the court stated: "If the nitrogen method is exploited to inflate protein

amount, plaintiffs alleged that the protein claim was misleading because the defendant added in non-essential amino acids that are high in nitrogen but of little nutritional value. *Id.*, at *5–6. This allowed the defendant to claim a higher protein content than the products actually delivered. *Id.* The defendant argued that the claim was preempted, because the "regulations permit manufacturers to calculate the total amount of protein" using the nitrogen method. *Id.*, at *14–15. The court rejected this argument and held that the claim was "not preempted" because plaintiffs plausibly alleged that "defendants failed to account for the protein quality in making the front-label statement, resulting in the type of false or misleading statement prohibited by § 101.13(i)(3)." *Id.* at *17–18.

*Ulrich* similarly dealt with a claim in which the defendant added low quality collagen proteins to its products, which "result[ed] in Products that effectively had less protein than they advertise" because "collagen protein is less digestible." *Ulrich*, 2017 U.S. Dist. LEXIS 132202, at *9–11. The court held that the claims were "not preempted." *Id.* at *12. As the court reasoned, "it appears to be a fair inference that [the] use of collagen protein isolate in its blend of proteins must have reduced digestibility of the protein in the Products" and it may "be misleading in a particular context to use the nitrogen method" which violates § 101.13(i)(3). *Id.* at *10–11.

Plaintiffs' claims here are identical to *Ulrich* and indistinguishable from *Porter* as far as preemption is concerned. Perfect Bar uses low quality protein sources in its products that have PDCAAS scores of between 0.4 and 0.5. ECF 1 ¶ 29. Nutritionally speaking, this means that Perfect Bar's products provide *less than half* of the protein they advertise in digestible form. ECF 1 at ¶ 19. Because Perfect Bar's front labels state a standalone protein *quantity* figure and do not give consumers *any* insights into the actual *quality* of the protein *anywhere* on the packaging, the front labels mislead consumers about the amount of protein they will actually receive from consuming the product. This violates 21 C.F.R. § 101.13(i)(3), and parallel state law in the form of the UCL fraud prong and the CLRA.

content, then *the amount of protein listed on the front label* may be false or misleading." *Porter II*, 2019 U.S. Dist. LEXIS 190495, at *10.

At first blush, it may seem incongruous that an FDA-approved testing method for inside the NFP could be misleading when stated elsewhere on the packaging. However, a dive into the FDA regulations and official agency commentary makes clear that that is the precise dichotomy the FDA envisions. *See also, Porter II*, No. 15 CV 11459, 2019 U.S. Dist. LEXIS 190495, at *9 (N.D. Ill. Nov. 4, 2019) ("That a protein-content calculation might be misleading when on the front label but permitted in the nutrition panel does not mean plaintiffs' theory fails as a matter of law."). The reality of the situation is that the FDA chooses the testing methodology that it approves for use in the NFP based on a variety of different factors, including the cost of the method, its widespread or limited availability, the accuracy of the test, and how important that accuracy is in the context of the given food product. It does not select a testing methodology because it can *never* be misleading, and the regulations are designed to take this fact into account. For example, as the FDA explained when it promulgated § 101.9(c)(7), it generally permits the nitrogen method *not* because it has determined the method is inherently non-misleading in all contexts, but because it is cheap, and "[b]ecause protein intakes generally are adequate and not a public health concern for" adults, meaning that accuracy was not that critical. 58 Fed. Reg. 2079, at 2102. As such, FDA decided that the "additional costs associated with determination of the PDCAAS ... are not warranted" most of the time. *Id*. However, if a party advertises a product by making a front-label protein claim, then the rules change, and the expense of PDCAAS is warranted precisely to ensure that consumers are not "*misled* by information on only the *amount* of protein present." *Id*. (emphasis added).

Because the considerations for what is appropriate to include in the NFP and what is an appropriate basis to market a product can be different, the FDA created two sets of rules: one for inside the NFP and one for front label claims about nutrients. The FDA went out of its way in enacting § 101.13(c) to provide that the information stated inside the NFP does not constitute a nutrient content claim and, therefore, is exempt from the special rules that apply to nutrient content claims. But, if that same information is stated elsewhere on the packaging, it becomes a nutrient content claim and may only be stated on the front package if it complies with all of the provisions § 101.13. One of those provisions, § 101.13(i)(3), clearly contemplate that stating a

pure "amount or percentage of a nutrient" can sometimes be "misleading," and despite the fact that the NFP is essentially populated *only* with amounts and percentages. This is why the Ninth Circuit, in interpreting these very regulations, has explicitly held that "a requirement to state certain facts in the nutrition [facts] label is not a license to make that statement elsewhere on the product." *Reid*, 780 F.3d at 960.

In the context of a low quality protein product, stating the quantity of protein alone, based solely on the nitrogen method is misleading in at least one respect—it misleads consumers about how much protein they will actually receive from the product. The FDA has explicitly stated as such in published guidance. In other words, this is one of the precise circumstances that the FDA envisioned in enacting 101.13(c) and (i)(3), and creating a scheme whereby the ability (or requirement) to put a statement in the NFP does not translate into an automatic right to use that same statement on the front of the package to advertise the product. Plaintiff's claim imposes identical requirements to those of the FDA under §§ 101.13(c) and (i)(3), and is therefore not preempted.

Many of Perfect Bar's arguments stem from a fundamental misunderstanding about Plaintiffs' theory of liability. Perfect Bar repeatedly states that Plaintiffs' claim requires its front label number to "be adjusted for digestibility using" PDCAAS. *See* ECF 20 at 9–10, 14–15. Plaintiffs' deception theory, however, is *not* that Perfect Bar *must* state anything at all about protein on its front labels. Rather, Plaintiffs' theory is that Perfect Bar was prohibited from making the claims that it did because they are misleading in violation of parallel state and federal requirements. As a result, there are a variety of ways that Perfect Bar could have made its labels not misleading in compliance with the regulations. These include making no protein claim, stating protein based solely on the PDCAAS method, or by using some combination of both methods (e.g., "6g total protein, 2.5g digestible protein"). But, as it stands now, Perfect Bar's labels fail to account for quality in any manner, which makes them misleading in violation of § 101.13(i)(3).

Perfect Bar argues that recent opinions in this district finding in favor of preemption—*Nacarino, Nature's Path, Van's International Foods*, *Chong*, and *Swartz*—control the outcome here. They do not. As *Nacarino* itself notes, numerous other courts have ruled the opposite way,

finding that similar claims are not preempted. 2022 U.S. Dist. LEXIS 23409, at *11 (citing cases). *Chong* was decided after *Nacarino* and essentially adopted its reasoning without much discussion. *See Chong*, 2022 U.S. Dist. LEXIS 277438, at *9.

*Nacarino* agreed with the general premise that nitrogen-based front label protein claims "may well be 'misleading' in the colloquial sense" due to the way low quality proteins operate in the human body. 2022 U.S. Dist. LEXIS 23409 at *7–8. It nevertheless concluded that such claims could never be misleading in the "regulatory sense" of § 101.13(i)(3). *Id*. According to the Court, the claims were not misleading in the "regulatory sense" because § 101.9(c)(7) "authorizes" a manufacturer to state protein quantity via "the nitrogen-content method without quality adjustment . . . in the Nutrition Facts label" and "to hold otherwise would be to find that an FDA-approved protein measurement technique is inherently misleading." *Id.* The remaining cases—*Nature's Path*, *Van's International Foods*, and *Swartz*—adopted *Nacarino's* reasoning on essentially identical grounds.

As explained above, *Nacarino*'s reasoning conflicts directly with FDA's official opinion that "protein quantity alone can be misleading on foods that are of low protein quality**."** 58 Fed. Reg. 2079 at 2101–2. Indeed, how the human body utilizes protein and whether that is accurately reflected in various protein measurement techniques is clearly within the FDA's "scientific expertise" and *Nacarino* should not have substituted its "judgment for that of the agency" on whether an FDA approved technique can be misleading in particular contexts. *Friends of the Santa Clara River v. United States Army Corps of Eng'rs*, 887 F.3d 906, 924 (9th Cir. 2018). Given FDA's official position, *Nacarino*'s distinction between misleading statements in the "colloquial sense" versus those in the "regulatory sense" is a mistaken one. FDA makes clear that claims like Perfect Bar's may be misleading in both senses.

*Nacarino* is also flawed because "[a] regulation cannot be susceptible to a construction that ignores or renders meaningless parts of its language." *Mont. Air Chapter No. 29, Ass'n of Civilian Technicians, Inc. v. Fed. Labor Relations Auth.*, 898 F.2d 753, 762 (9th Cir. 1990). But *Nacarino*'s conclusion that a testing methodology is inherently non-misleading so long as the FDA has approved it for use in the NFP renders §§ 101.13(c) and 101.13(i)(3) meaningless. If

*Nacarino*'s interpretation were correct, then any information from the nutrition facts panel would automatically qualify as a permissible front-of-pack nutrient content claim because all of those figures are necessarily supported by an FDA-approved testing methodology. But the FDA went out of its way in § 101.13(c)—which *Nacarino* did not discuss—to make clear that information stated in the NFP does *not automatically qualify* as a nutrient content claim and in § 101.13(i)(3) that it may sometimes be "misleading" in some respects. This is one of those times.

**i. This case presents exceptional circumstances akin to *Reid* and *Hawkins*.**

*Nacarino*, *Chong*, and their progeny do not bind this Court. But the Ninth Circuit opinions in *Reid* and *Hawkins*, which addressed the issue within the trans fat context, are binding.

In *Reid*, the products contained approximately 0.5 grams of trans fat per serving, which NFP regulations permitted to be rounded to "0 grams of trans fat" for the back panel. *Reid*, 780 F.3d at 963. The defendant stated "No Trans Fat" on the front label, which it contended was permissible because it was "synonymous" with what FDA regulations *required* for the NFP. *Id.* The Ninth Circuit agreed the statements were equivalent, but held "it makes no difference here." *Id.* "While a required statement inside a nutrition label escapes regulations reserved for nutrient content claims, *the identical statement outside of the nutrition label is still considered a nutrient content claim and is therefore subject to section 101.13*," which prohibits amounts and percentages from being misleading in any respect. *Id.* (emphasis added). Since the defendant's products contained up to 0.5 grams of trans fat per serving, "its 'No Trans Fat' claim is misleading in at least one respect." *Id.* Accordingly, the regulations specifying what was permissible within the NFP did not preempt the plaintiff's claims about what was misleading on the front of the package. *Id.* In *Hawkins*, the Ninth Circuit extended this point to the front label statement "0 grams trans fat per serving," which was *identical* to the statement *required* in the NFP. 906 F.3d at 766, 771–72.

As in *Reid* and *Hawkins*, Perfect Bar's front label claims are misleading in violation of § 101.13(i)(3) and parallel state laws, so the existence of regulations permitting Perfect Bar to make protein quantity statements alone inside the NFP does not preempt Plaintiffs' claims as to the front of the package.

*Nacarino* found that *Reid* and *Hawkins* both state the "exception, not the rule" to whether NFP statements can qualify as nutrient content claims. 2022 U.S. Dist. LEXIS 23409, at *10. But even if that were true generally, *Nacarino* ignores that this case also presents such an "exception." This case centers *specifically* on products made up of low quality proteins. Plaintiffs' position is *not* that nitrogen-testing is always or inherently misleading. If a product consists of high quality proteins, nitrogen testing can provide an accurate, non-misleading picture of protein content. The problem arises when a product consists of low-quality proteins like Perfect Bar's. In that scenario, nitrogen testing yields inflated numbers. It suggests that consumers will receive all the protein claimed, even though that is simply not true. Here, over half the protein is useless to humans. ECF 1 at ¶ 19. While the raw protein quantity may be true in the abstract, it is fundamentally misleading when stated without any context as to its quality.

Moreover, as in *Reid* and *Hawkins*, where the FDA had issued guidance calling into question front of pack "no trans fat" claims, the FDA here has also issued guidance explicitly recognizing that "protein quantity alone can be misleading on low quality protein products." In other words, the FDA recognizes the problem and it structured its regulations to address it both in the NFP through § 101.9(c)(7)(i)–(iii) and on the front through §§ 101.13(c) and 101.13(i)(3). *Nacarino* also distinguished *Reid* and *Hawkins* on the basis that the claims "were uncontrovertibly false in a way that the claim in this case is not: It is not true to say that a product does not contain fat when it does." *Nacarino*, 2022 U.S. Dist. LEXIS 23409, at *11. But, the regulation at issue in this case—§ 101.13(i)(3)—does not prohibit only "uncontrovertibly false" claims; it prohibits *misleading* claims too. By definition, a claim is misleading when "although true, [it] is either actually misleading or [] has a capacity, likelihood or tendency to deceive or confuse the public." *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1162 (9th Cir. 2012). So, the fact that this case may not present a literal falsity is of no moment. *Nacarino* necessarily found that front label protein claims may be misleading in this sense. 2022 U.S. Dist. LEXIS 23409, at *7. And, as explained above, the FDA agrees. This precludes preemption.

Perfect Bar claims that industry guidance the FDA published on its website ("FDA webpage") supports its position. ECF 18 at 1; RJN, Ex. 1. Perfect Bar also directs the Court to

recent decisions ruling in favor of preemption based on the FDA webpage. ECF 18 at 1, n.1 (*citing Chong*, --- F. Supp. 3d ---, 2022 U.S. Dist. LEXIS 27438, at *6–9; *Nature's Path Foods, Inc.*, 2022 U.S. Dist. LEXIS 42760, at *15–17; *Swartz*, 2022 U.S. Dist. LEXIS 99226, at *10–12; and *Van's Int'l Foods*, 2022 U.S. Dist. LEXIS 84477, at *15–16. In *Nature's Path*, which is representative of the reasoning of all four decisions Perfect Bar cites, the court determined that the FDA webpage "clarifie[s] that protein content claims may be based on 'either of the methods mentioned' in section 101.9(c)(7)—that is, the 'nitrogen method' or the 'protein digestibility-corrected' figure." *Id*. *Nature's Path* held that preemption was warranted because "the FDA has now made clear that its regulations do not require protein content claims to adjust for digestibility or to be calculated using amino acid contest testing."[6] *Id*.

This interpretation of the FDA webpage is flawed for a number of reasons. First, the FDA webpage does not pronounce a blanket rule that nitrogen testing is *always* allowed for front label claims. Nor could it because it does not even consider the primary regulation at issue in this case: § 101.13(i)(3)'s prohibition against false or misleading claims. As explained above, nitrogen testing can be an accurate method for some foods, such as those consisting of high quality proteins, but it is misleading when used for foods with low quality proteins, like Perfect Bar's.

Further, *Nature's Path* and its related cases miss the context of the FDA webpage. The FDA webpage purports to interpret § 101.13(o), the regulation about *compliance*. Both § 101.13(o) and the FDA webpage's discussion of it are irrelevant because "determining compliance" presupposes that the claim is *already authorized* by the nutrient content claim regulations. But § 101.13(b) is clear that a nutrient content claim "may not be made on the label" if it violates *any* of the provisions of § 101.13. Nothing on the webpage or in § 101.13(o) says that manufactures are now absolved from meeting these other requirements by using a testing method referenced in § 101.9(c). Indeed, such an interpretation would make no sense given § 101.13(c), and would render it meaningless. Instead, the only way to construe 101.13(o) in light of the rest of 101.13 is to determine it comes into play only once a claim satisfies all of these other

[6] Like Perfect Bar, the court in *Nature's Path* misinterpreted 'the plaintiffs' claims. Plaintiffs do not allege that Perfect Bar should "adjust" the front number for digestibility. *See supra*, 11.

provisions, including § 101.13(i)(3). In that light, the FDA webpage is perfectly consistent with Plaintiffs' claims. Where nitrogen testing is non-misleading, such as on high quality proteins, it can be used to advertise protein quantity on the front. When PDCAAS is non-misleading, it can be is used instead. Or, as Plaintiffs noted above, both could be used to avoid being misleading.

Moreover, in *Kisor*, the Supreme Court admonished lower courts for doing exactly what the courts cited by Perfect Bar did, which is abdicate their responsibility to interpret regulations in favor of unofficial agency statements. *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). Under *Kisor*, the Court cannot do so unless, after deploying all the interpretative methods in the "legal toolkit," the court finds that the regulations are "genuinely ambiguous," and then only if the proffered interpretation is reasonable, and represents the *official* position *of the agency*. *Id*. at 2405–06. Unless all of these are satisfied, the Court cannot give the proffered interpretation *any* weight.

Here, the FDA webpage here is not official agency position set forth in the federal register. Nor are the regulations at issue "genuinely ambiguous." Section 101.13(o)—the regulation the webpage interprets—provides that "compliance with requirements for nutrient content claims …will be determined using *the* analytical methodology [singular] prescribed for *determining compliance* with nutrition labeling in § 101.9." This does not refer to the multiple testing methodologies (plural) described in § 101.9 to *measure* nutrients; rather, it incorporates by reference *the* one analytical methodology the FDA uses for *determining compliance*—i.e., § 101.9(g), which states "Compliance with this section shall be determined as follows . . ." and then sets forth the 12-sample size requirement, recordkeeping obligations, and the like.

Defendant also relies on two emails submitted in other cases wherein defendants hired lawyers to email their former colleagues at the FDA. (ECF 18 at 4.) Those emails are not suitable for judicial notice. (See Plaintiffs' Opposition to Defendant's Request for Judicial Notice, to be filed concurrently with this opposition.) Furthermore, *Kisor* forecloses giving any sort of deference to these unofficial "interpretations." Defendant also neglects to disclose that the courts in which the emails were originally submitted refused to defer to the "interpretations" proffered therein. *See Chong*, 2021 U.S. Dist. LEXIS 182395 at *2; *Nacarino*, 2022 U.S. Dist. LEXIS 23409 at *12, n.3. Those emails should not be considered.

## V. CONCLUSION

For the foregoing reasons, the Court should deny Perfect Bar's Motion to Dismiss.

Dated: July 1, 2022

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